REMARKS

Reconsideration of this application in view of the following remarks is requested. After entry of this reply, claims 1-21 and 30-38 are pending in the application. Claims 22-29 are canceled, and claims 32-38 are added.

Please note and record our change of Attorney Docket Number in this matter to: 126066-00101.

Applicant's representative would like to thank the examiner for his time and cooperation during discussions concerning the office action and the issues presented therein. Further to those discussions, applicant's representative reminds the examiner to contact him during further examination of this application, and prior to issuance of the next office action.

In the office action dated March 23, 2006, the examiner rejects claims 22 and 27 under 35 USC § 102(b) as anticipated by Xavier (U.S. Patent No. 5,458,631); rejects claims 28 and 29 under 35 USC § 102(b) as anticipated by Galindo (U.S. Patent No. 4,411,657); and rejects claims 23-26 under 35 USC §103(a) as unpatentable over Xavier (U.S. Patent No. 5,458,631); and rejects claims 1-21 and 30-31 under 35 USC §103(a) as unpatentable over Klein et al. (Anesth Anal 2000; 91:1473-1478) in view of Xavier (U.S. Patent No. 5,458,631).

Claim Rejections – 35 USC § 102

Applicant respectfully traverses the examiner's rejections of claims 22 and 27 under 35 USC § 102(b) as anticipated by Xavier (U.S. Patent No. 5,458,631), and rejects claims 28 and 29 under 35 USC § 102(b) as anticipated by Galindo (U.S. Patent No. 4,411,657).

However, for reasons unrelated to patentability, applicant cancels these claims, solely to expedite prosecution of the application.

Claim Rejections – 35 USC § 103

The examiner rejects claims 23-26 under 35 USC §103(a) as unpatentable over Xavier (U.S. Patent No. 5,458,631), and rejects claims 1-21 and 30-31 under 35 USC §103(a) as unpatentable over Klein et al. (Anesth Anal 2000; 91:1473-1478) in view of Xavier (U.S. Patent No. 5,458,631).

Applicant respectfully traverses the examiner's claim rejections under 35 U.S.C. §103(a), as applicant denies that a prima facie case of obviousness has been established. Applicant contends that the examiner's statements appear conclusory, without adequate justification existing in Xavier, and Klein in view of Xavier, to substantiate the §103 rejections.

Regarding claims 1-21 and 30-31, the examiner states, at page 4 of the office action, that Klein discloses "a method of providing long term pain management that includes most of the limitations as recited in claims 1-21 and 30-31...However, Klein teach[es] to use a disposable infusion pump to deliver the drugs instead of an implantable infusion pump." The examiner continues: since Xavier discloses an implantable catheter and pump that provides long term pain management by infusing drugs into the epidural space of the patient, it would have been obvious to modify the method of Klein with the implantable pump of Xavier to make a method less prone to cause damage or infection to the patient. This reasoning is conclusory, as modifying the method of Klein with the implantable pump of Xavier would not lead to the claimed invention.

The question raised under 35 U.S.C. §103 is whether the reference(s) taken as a whole would suggest the claimed invention taken as a whole to one of ordinary skill in the art. Accordingly, the claimed invention taken as a whole cannot be said to be obvious without some reason given in the reference(s) why one of ordinary skill would have been prompted to modify the teachings of the reference(s) to arrive at the claimed invention. Therefore, some reason or suggestion must be found in the evidence of record that would have led one of ordinary skill in the art to produce the claimed invention in order to properly establish a prima facie case of obviousness. Klein and Xavier fail to provide the reason or suggestion.

Klein discusses supplementing an operative interscalene brachial plexus block of 1.5% mepivacaine with a postoperative intraarticular infusion of 0.5% ropivacaine at 2ml/h. Klein's teaching of a postoperative intraarticular infusion is over a duration of, at most, 48 hours from the operative interscalene brachial plexus block. Klein assesses visual analog scale pain scores and postoperative oxycodone consumption over those 48 hours for those receiving the 0.5% ropivacaine intraarticular infusion versus those receiving a saline intraarticular infusion.

Klein concludes (beginning at the bottom of column one of page 604) that "the reduced pain provided by intraarticular ropivacaine infusion can be attributed to avoidance of the rapid resolution of neural blockade and sudden development of pain from a previously analgesic site." As Klein's intraarticular ropivacaine infusion is taught to bridge the "rapid resolution of neural blockade," this conclusion teaches and suggests that Klein's method is directed to, and adequate for, only short term, acute postoperative pain, not for the long term, chronic pain management of the claimed invention. To be sure, added dependent claims 32

and 33 clarify long-term pain management, specifically reciting the delivering of medication for at least one week (claim 32) or for weeks, months or years (claim 33).

Further, Klein directs his study toward, and infers success of his 0.5% ropivacaine intraarticular infusion to, the intraarticular infusion's affect on lessening a patient's postoperative need for oxycodone (see Abstract and Figure 3). Klein, therefore, teaches away from the present invention, as the present invention advocates the use of opioids, antispasmodics, alpha 2 agonists and local anesthetics independently and in combination to promote long term, peripheral neural analgesia (see paragraph [0058] of specification). In fact, Klein's use and teaching of only ropivacaine confirms the disclosure of specification paragraph [0058] of the present invention, which states: "[b]upivacaine is a typical peripheral nerve analgesic, as are similar drugs such as tetracaine and lidocaine." The present invention, however, employs novel, diverse types of analgesics to a peripheral neural structure. To be sure, dependent claim 17 recites these diverse analgesic types (e.g., opioids, antispasmodics, alpha 2 agonists and local anesthetics), analgesics not taught or suggested by Klein (in fact, even taught away by Klein). Accordingly, the specific medications of the claimed invention, and the amount of each medication, are not simply a matter of design choice, as the examiner states in his rejection of claims 23-26 under 35 USC §103(a) as unpatentable over Xavier alone.

An obviousness rejection under §103 requires that the surrounding circumstances or evidence of record make any proposed modification over the reference(s) obvious to *do* rather than obvious to *try*. The examiner states that it would have been obvious to modify the method of Klein with the implantable pump of Xavier to make a method less prone to cause

damage or infection to the patient. The examiner makes this statement without any suggestion in Klein or Xavier that making the modification would result in the requisite expectation of success necessary to maintain a 35 U.S.C. §103 rejection.

The implanted catheter and pump of the present invention to deliver medications to a peripheral neural structure involve vastly different bodily spaces than the implanted catheter and pump of Xavier, and involve novel and different medicines, and different combinations of medicines, than the peripheral neural infusions of Klein. For example, nerve growth inhibiting medications of the present invention present half-life concerns differing from the disposable pump medication infusion of Klein, and the implantable pump medication infusions of Xavier. In addition, the nerve growth inhibiting medications require continuous use and fixed rate dosing concerns that Klein has not taught or suggested possible, that complicate an implanted system delivering to a neural structure, and perhaps explain why neither Klein nor Xavier suggest long term implanted pump medication delivery to a peripheral neural structure. In addition, long term catheter access to the varying neural structures, and the design mechanics of the implanted components to deliver to the neural structures, differ vastly from the abdomen only implantation and solely epidural medication delivery of Xavier.

Therefore, the examiner's conclusory statement of obviousness, without more, does not satisfy the burden of establishing a prima facie case of obviousness. One cannot base obviousness upon what a person skilled in the art might try or might find obvious to try but rather must consider what the reference(s) would have led a person skilled in the art to do successfully.

Furthermore, when evaluating a claim for obviousness, all limitations of the claim must be considered. Neither Xavier or Klein, either alone or in combination, disclose, teach or suggest an implanted catheter and pump, where the catheter discharges to a peripheral neural structure, and the pump operates to deliver continuous medication to the peripheral nerves, providing long term, chronic pain management.

Regarding exemplary dependent claims, even Klein's purported teachings of temporary medication delivery with a disposable pump to peripheral nerves, does not disclose or teach delivery to the peripheral nerves featured in claims 8 through 13. Nor does Klein teach or suggest the delivery to peripheral nerves of the medications featured in claim 17, nor the doses featured in added claim 34.

For the foregoing reasons, applicant contends that a prima facie case of obviousness has not been established. Accordingly, the examiner is respectfully requested to withdraw the §103 rejections based upon Klein, or upon Klein in view of Xavier.

Claims Added by this Response and Amendment

Claims 32-38 are added to more completely cover certain aspects of applicant's invention. The recitations of claims 34-38 were previously included in one or more of the pending or canceled claims. The dosage duration features of claims 32, 33, 37 and 38 find support in at least paragraph [0058] of the specification. The added claims are patentable over the prior art of record for all of the reasons discussed in the Remarks above.

CONCLUSION

In light of the above amendments and remarks, applicant submits that pending claims 1-21 and 30-38 are allowable, and requests that the examiner issue an early notice of allowance. Again, the undersigned attorney requests that the examiner call during review of this response and amendment.

Respectfully submitted,

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